AHLA

The Opioid Crisis

Understanding the Complexities, Acknowledging the Challenges, and Exploring Possible Solutions

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I. Introduction

The American Health Lawyers Association (AHLA) hosts nonpartisan expert panel convener sessions in order to provide a neutral forum for the frank and candid exchange of views and analyses among invited experts on select health care policy issues that have a clear legal nexus. White papers and supplemental resources often result from these convener sessions. These sessions underscore AHLA's commitment to promote a better understanding of health care issues and to encourage constructive dialogue among all affected industry stakeholders, government, academia, and the lay community.

On September 25, 2018, AHLA hosted a convener session at American University's Washington College of Law in Washington, D.C. to address the national crisis of opioid-related harm. Twenty experts from around the country gathered for a day-long meeting to identify the most pressing issues and discuss possible solutions. The participants in attendance represented a diversity of backgrounds, expertise, and viewpoints on the crisis. They included representatives from federal agencies, including the U.S. Department of Health and Human Services and the U.S. Department of Justice; health insurance payers; professors and physicians from major academic medical centers; advocacy organizations and trade associations for physicians, pharmacists, and other professionals; first responders; state health agencies; and health law attorneys. Convener participants were all individuals at the forefront of the opioid crisis, and they presented their individual viewpoints on the subject.

This white paper captures the major themes and recurring issues that convener participants—with their diverse experience, expertise, and perspectives—discussed and debated during the day-long session. It offers a range of feasible and practical options and solutions (**highlighted in bold**) that were suggested as a result of the healthy dialogue that took place—options and potential solutions that political leaders, community activists, and patient advocates may want to consider and tailor to the current needs of their communities. Importantly, AHLA has not fact checked, critiqued, or commented upon any of the statements or proposals made by any participants at the convener session. Our intention is, instead, to objectively report the salient points made by the convener participants so that the reader can have the benefit of the unfiltered discussion from that day. Given the nature of convener discussions, this white paper includes statements that reflect everything from a broad consensus of all participants to the view of an individual participant. AHLA also has not endeavored in this white paper to bring the discussion forward past September 25, 2018 when the convener occurred. For supplemental information about the opioid crisis, readers are encouraged to refer to the *Opioid Crisis* page on

AHLA's web site at https://www.healthlawyers.org/find-a-resource/HealthLawHub/Pages/Opioids.aspx. The website contains reference material that delves more deeply into many of the issues addressed at the convener session.

II. An Overview of Legislative and Administrative Activity

The convener was held against the backdrop of a bipartisan effort at the federal level to address the opioid crisis on multiple fronts, which culminated in the enactment of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).[1] President Donald Trump signed the Act into law on October 24, 2018 after it cleared the House of Representatives and Senate by substantial margins. The SUPPORT Act was the third of significant federal enactments over the last several years, which include two 2016 laws: the Comprehensive Addiction and Recovery Act (CARA)[2] and the 21st Century Cures Act (CURES Act).[3]

The SUPPORT Act contains wide-ranging provisions and reforms to combat the opioid crisis by advancing treatment and recovery initiatives, improving prevention, and protecting communities. The law seeks to deter the powerful synthetic opioid fentanyl from entering the country, help establish opioid-specific recovery centers, increase access to housing and work opportunities for those in recovery, expand access to medication-assisted treatment (MAT), and increase Medicaid coverage of treatment for substance use disorders, among many other provisions.

Congress also devoted additional funds to the opioid crisis in the fiscal year 2019 spending package, which includes a $2 billion increase for the National Institutes of Health and $3.7 billion in funds targeted toward improving treatment and prevention efforts for opioid addiction; finding alternative pain medications; workforce needs; and expanding access to behavioral health services. The spending measure also provides $3.4 billion for mental health research, treatment, and prevention; $1.63 billion for Community Health Centers; and $318.8 million for rural health care programs.[4]

While these efforts have been viewed as significant steps to addressing the opioid crisis, the SUPPORT Act did not adopt several provisions in its final package of

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[1] SUPPORT for Patients and Communities Act, Pub. L. No. 115-271 (2018), https://www.congress.gov/bill/115th-congress/house-bill/6/all-info.
[2] Pub. L. No. 114-198 (2016), https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf.
[3] Pub. L. No. 114-255 (2016), https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf.
[4] House Appropriations Committee, *Summary of FY 2019 Defense and Labor-HHS-Education Appropriations Minibus,* Sep, 14, 2018, https://appropriations.house.gov/news/press-releases/summary-of-fy-2019-defense-and-labor-hhs-educations-appropriations-minibus.

reforms that may be the focus of future legislative or regulatory activity. For example, the final SUPPORT Act did not include a proposed provision that would have amended the Confidentiality of Alcohol and Drug Abuse Patient Records (with implementing regulations at 42 CFR Part 2) to better align confidentiality protections with those in the Health Insurance Portability and Accountability Act (HIPAA). This provision is controversial, with advocates for an amendment arguing that the change is needed to facilitate treatment and research requirement, but opponents voicing serious concerns that an amendment to eliminate the requirement for specific consent to share records may deter patients further from seeking treatment for substance use disorders. Furthermore, some observers believe that the SUPPORT Act also suffers from a continued focus on opioid prescribing alone and largely ignores issues of substance switching and multi-class drug misuse. Those who have this viewpoint believe it significantly enhances surveillance of opioid prescribing practices in a way that may lead prescribers to abandon even appropriate prescribing and drive patients to illicit drug use.

Federal agencies also have increased their focus on responding to the opioid crisis, including new funding awards, guidance, and additional rulemaking. In September 2018, the Department of Health and Human Services (HHS) awarded $1 billion in opioid-specific grants. As part of the awards, the Substance Abuse and Mental Health Services Administration (SAMHSA) allotted more than $930 million to states to increase access to MAT using the three Food and Drug Administration approved medications for the treatment of opioid use disorder. The Health Resources and Services Administration (HRSA) awarded more than $396 million to enable HRSA-funded community health centers, academic institutions, and rural organizations to expand access to integrated substance use disorder (SUD) and mental health services. In addition, the Centers for Disease Control and Prevention awarded over $155 million to increase support for states and territories working to prevent opioid-related overdoses, deaths, and other negative outcomes.[5]

HHS also developed materials with the Drug Enforcement Administration (DEA) to help clarify how providers can use telemedicine to expand buprenorphine-based MAT for opioid use disorders under current DEA regulations.[6] These materials clarify that buprenorphine may be prescribed outside of a face-to-face interaction, which may increase access to this life-saving medication, particularly for individuals in rural areas and others who have difficulty accessing a buprenorphine prescriber.

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[5] HHS PRESS OFFICE, *HHS AWARDS OVER $1 BILLION TO COMBAT THE OPIOID CRISIS*, SEP, 19 2018, https://www.hhs.gov/about/news/2018/09/19/hhs-awards-over-1-billion-combat-opioid-crisis.html

[6] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVS., *Telemedicine and Prescribing Buprenorphine for the Treatment of Opioid Use Disorder* (Sept. 2018), https://www.hhs.gov/opioids/sites/default/files/2018-09/hhs-telemedicine-hhs-statement-final-508compliant.pdf.

The HHS Office for Civil Rights (OCR) in 2017 issued guidance[7] on sharing protected health information (PHI) in crisis situations, but "continues to receive anecdotal evidence that providers and other covered entities are reluctant to share an opioid patient's health information with family or other caregivers." To address this issue, OCR is planning to issue a proposed rule in 2019 further clarifying the HIPAA privacy rule provisions applicable to information sharing with family members or caregivers when patients are incapacitated.

Although the SUPPORT Act did not amend 42 CFR Part 2, SAMHSA is working on a proposed rule that would make broad changes to the privacy rules for SUD records. According to SAMHSA, these changes would be aimed at removing barriers to coordinate care and permitting additional information sharing among providers and programs assisting patients with SUDs. SAMHSA acknowledged that the proposed rule, which is anticipated in 2019, may raise concerns among stakeholders about undermining privacy protections under the 42 CFR Part 2 regulations.

States have also been working to address the crisis. According to the National Conference of State Legislatures, as of October 2018, 33 states have enacted legislation that provides guidance or limitations on opioid prescriptions.[8] Six states have binding restrictions and many states have enacted legislation that limits first-time opioid prescriptions to a seven-day supply. However, some states do provide exceptions.[9] Some states have adopted other measures in addition to prescribing limitations. For example, Michigan recently adopted laws mandating that prescribers have specific conversations with patients for whom opioids are being prescribed to discuss the drug's habit-forming potential and proper use,[10] and that those patients be required to sign a document acknowledging that they understand the information imparted as a precondition to receiving the prescription. Other examples of state activity were discussed by the convener participants throughout the day, which are described in the later sections of this white paper. Additional information about state activities can be found in the *Opioid Crisis* page on AHLA's website.

Without a comprehensive approach to the complex and interwoven issues involved in the opioid crisis, overall reductions in morbidity and mortality are unlikely to

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[7] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVS. OFFICE FOR CIVIL RIGHTS, *How HIPAA Allows Doctors to Respond to the Opioid Crisis* (Oct. 2018), https://www.hhs.gov/sites/default/files/hipaa-opioid-crisis.pdf.

[8] National Conference of State Legislatures, *Prescribing Policies, States Confront Opioid Overdose Epidemic*, (Oct. 31, 2018), http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx.

[9] *See* ARIZ. REV. STAT. § 32-3248; N.C. GEN. STAT. § 90-106.

[10] MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS (LARA) AND THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS), *MICHIGAN OPIOID LAWS*, JANUARY 2019, https://www.michigan.gov/documents/lara/LARA_DHHS_Opioid_Laws_FAQ_05-02-2018_622175_7.pdf.

materialize. Despite the considerable governmental activity outlined above, convener participants acknowledged that opioid misuse remains a multi-faceted health crisis in the United States. The early attention on prescription opioids alone achieved some reductions in overdoses related specifically to prescription opioids. Nonetheless, these efforts may not have effectively reduced overall harms. Opioid related overdoses are still at record highs as people who misuse opioids or have substance use disorders turned to other sources, such as illicit opioids. While opioid related deaths may have declined in some states, convener participants agreed that the overall death rate and non-fatal negative consequences of opioid misuse is still significant and troublesome. Therefore, convener participants strove to offer holistic, innovative ideas reaching beyond the scope of existing governmental actions. These were offered with the hope that outside-the-box thinking may assist policymakers as they continue to combat opioid-related harms and their broad negative consequences.

III. Overarching Barriers to Effective Solutions —Data Gaps, Social Stigma, Prescribing Practices, and the Impact of Payer Policies

A. Data Gaps

While there is much data available on the opioid crisis, existing data on myriad aspects of the crisis is incomplete, inconsistent, or non-existent, hampering effective policy development and evaluation of enacted policies. Current data regarding opioid-related events (non-fatal overdoses, hospital visits, deaths, and opioid related morbidity)—including the effectiveness of legislation and policies designed to address the crisis—is often incomplete and outdated. Accurate and comprehensive data is unquestionably important for the development of appropriate policies.

Many factors contribute to these gaps in data. Some of the most frequently stated reasons, as discussed by the convener participants, are highlighted below:

1) Some negative events are never reported because calling 911 is avoided due to fear of being arrested for participation in criminal activity involving opioids. This causes statistics on opioid-related events to become artificially deflated.
2) First responders must often "treat and release" at the scene. Information about the individual cannot always be captured in these types of scenarios, making comprehensive data collection and follow-up care extremely challenging, if not impossible.
3) An apples-to-apples comparison of outcomes (and effectiveness) of current policies being implemented at local, state, and national levels is typically not possible given the numerous disparate data systems being used to collect different pieces of information. For example, some rural state agencies lack resources for electronic prescribing, which can result

in homegrown prescribing systems that cannot link up to larger health record systems like EPIC.

4) Patient privacy laws can make it difficult for health care providers to access information about individuals who have been treated previously for an opioid overdose at another hospital or facility.
5) National data regarding opioid statistics and reports on the effectiveness of implemented policies are generally outdated by the time local communities receive the data. Convener participants generally agreed that local communities need to receive this information in a more timely fashion.
6) Information entered into each state's Prescription Drug Monitoring Program (PDMP) is not standardized, and manual entry of information leaves room for human error. In addition, the experience of many convener participants is that extracting information from PDMPs that may be helpful in a provider's effort to treat an individual can be a time-consuming and cumbersome effort. More importantly, some convener participants noted that data is still lacking on the overall effectiveness of PDMPs in reducing overall opioid related morbidity and mortality.
7) A patchwork of state laws regarding prescribing practices and dosage limits impacts continuity of care, further contributing to the creation of data gaps when it comes to providing effective patient care.

B. <u>Social Stigmas and Individual Biases</u>

Convener participants engaged in a robust discussion surrounding stigmatization of people with substance use disorders, chronic pain, and related conditions, which includes both self-stigma and social stigma (desire to avoid others with or perceived to have the condition). Convener participants generally agreed that individuals with chronic pain and/or substance use disorder suffer significant health consequences due to self-stigmatization and perceived stigma from others. There is an extensive body of literature documenting the stigma and associated individual biases attached to substance use disorders, and this stigma often extends to those who have achieved stable recovery. Convener participants noted that this stigma is demonstrated in a wide range of attitudes, behaviors, policies, and laws, and has been identified by researchers and providers as a major obstacle to personal and family recovery. Stigma impacts the allocation, type, and magnitude of economic, cultural, and other resources available to address substance use issues.

Convener participants agreed the reasons why individuals do not seek treatment for opioid use disorder are varied and wide-ranging. The shame of needing help for opioid use disorder plays a large role in preventing individuals from seeking treatment. In addition, policies that are punitive can perpetuate the stigma associated with opioid use disorder. A convener participant reported that in Massachusetts, for example, an individual can be involuntarily committed for treatment under state law, which can deter persons from seeking treatment at emergency departments.

Per convener participants, the cultural attitudes, historical treatment, and other factors that contribute to and exacerbate stigma impact the interactions between health care providers and patients as well. For example, patients often report perceived stigma in health care interactions.

Some participants discussed the "association stigma" for providers who care for people with substance use disorders—meaning that providers perceive stigma from other health care providers because they chose to "associate" with members of the stigmatized group. Moreover, the stigmatization of people with substance use disorders likely impacts provider decision making on an unconscious level, leading to diagnostic and treatment errors, and it may also contribute to mistreatment and inequities in care among this group.

Convener participants discussed their view that other policies, while well meaning, can create unintended negative results. For example, employers' policies on maintaining a drug-free work environment can hamper an individual's ability to re-enter the work force. Although individuals in treatment should be protected by anti-discrimination laws, once the individual has been identified as undergoing an addiction treatment program, they may nonetheless suffer stigmatization and discrimination. While convener participants believed that mental health parity laws are a positive step forward in terms of "normalizing" treatment for substance use disorders, they also felt that consistent enforcement of those laws has been challenging.

A major and recurring theme throughout the entire day of convener discussions was the lack of education in medical, dental, and nursing schools regarding substance use disorders, which likely affects the recognition and treatment of the condition, as well as how patients with substance use disorders are perceived and treated by the health care provider community. Convener participants reported that most medical students received very limited training about pain management and substance use disorder. For example, one convener participant referenced a University of Pennsylvania study showing that most medical students receive only one hour of training on pain management and zero hours on addiction disorders. Convener participants generally agreed that there was a lack of instruction in this area; they further noted that practicing physicians also report feeling unprepared to treat substance use disorders and often hold inaccurate, outdated beliefs regarding treatment. It was reported that very few states require training as part of continuing medical education. Per convener participants, additional training and education may help de-stigmatize substance use disorders by, for example, facilitating an approach to substance use disorders as treatable chronic health conditions rather than criminal behaviors.

Some convener participants commented that education on the use of non-stigmatizing and patient-centered language is also essential. For example, individuals should be described as patients with substance use disorder rather than

addicts or substance abusers. Some convener participants even believed the term "substance abuse" should not be used. Documentation should also reflect a commitment to non-stigmatizing, non-blaming language. For example, phrases like "patient failed to respond to alternative treatments" implicitly blames the patient.

C. *Attempts to Define "Inappropriate Prescribing" and the Impact of Current Prescribing Guidelines on the Provider Community*

To the extent that "inappropriate prescribing" of opioids contributes to the opioid crisis, the first question that comes to mind is how do we identify prescribing practices that are in fact inappropriate? Convener participants offered a variety of thoughts about whether it is possible to define such practices, and if so, what data points and analyses are needed to distinguish appropriate from inappropriate prescribing behavior.

Convener participants also discussed whether a definition for inappropriate prescribing should exist at all. Without having a good understanding of what practitioner behavior is problematic, policy solutions may miss the mark entirely, or be over or under inclusive.

Convener participants discussed their perception that data collected as a result of state laws that focus uniquely on the quantity of pills prescribed often does not include contextual patient information that may have informed the provider's prescription choices. Convener participants believed that this makes it difficult to determine whether a provider is engaging in inappropriate prescribing or properly prescribing therapeutic opioids to meet a documented patient need. A majority of convener participants believed that any definition for inappropriate prescribing should be empirically based and take into account the patient's particular situation. At their core, prescribing decisions are best made in the purview of the individual provider-patient relationship, and in the specific context of the individual patient's clinical and social needs.

One suggestion was to evaluate prescribing by locality and by prescriber specialty. Convener participants discussed "stewardship programs" at the University of Chicago and Kaiser Southern California, for example, which collect *local* data on physicians' opioid prescribing practices and compare the patterns and numbers to their peers within the local regions. Per convener participants, this produces a more accurate apples-to-apples comparison that takes into consideration local community demographics and medical specialties that tend to prescribe a higher number of opioid-based medications than other specialties (e.g., oncology vs. internal medicine).

The State of Kentucky's PDMP structure was brought up as an example that might help both the provider community and the government more accurately determine whether inappropriate prescribing is taking place. A field variable in the state's PDMP helps to identify outliers, but also takes into consideration the prescribing

physician's medical specialty. PDMP administrators look to see if trend lines for a prescribing physician are remaining steady, experiencing a sudden spike, or gradually increasing over time. Data that goes beyond "population policy" helps to create well-informed prescribing standards and reimbursement structures.

Convener participants noted that it is unclear what the appropriate use of this PDMP data is with respect to physician prescribing. Should government authorities use this data to take adverse licensure action against practitioners whose prescribing practices are determined to be improper? One participant was concerned that even if the PDMP identifies a prescriber acting improperly or illegally, shutting down that prescriber without connecting her patients with other care may actually increase overdose risk.

A few participants emphasized that we should remain vigilant about evaluating success in terms of PDMPs. Even accurate, real time reporting PDMPs that require prescriber queries may not do more than relieve a prescriber's concerns about their own prescription. Some convener participants discussed whether the collection of PDMP data could have the negative unintended consequences of driving patients with substance use disorders to illicit and far riskier substances, ultimately leading to increased harm to the patient.

Another point of discussion was the multitude of pressures on treating providers, including time and financial constraints, lack of multi-disciplinary and alternative treatment options for their patients, fears about external scrutiny, and a trend toward systematizing prescribing without individual patient context. For example, the gold standard for pain treatment is multidisciplinary and requires lengthy communication and assessment. In reality, convener participants noted that few providers are afforded the ability to actually engage in this kind of care. The daily reality and struggle for health care providers was summed up as "so many patients and too little time." It is often easier and faster to write a prescription for opioids or discount the patient's reports of pain than to have a longer discussion or comprehensive evaluation. While all convener participants acknowledged this was not ideal, it is unfortunately the reality for many given providers' time constraints. The lack of reimbursement for best practices and alternative therapies was also identified as a significant barrier to better patient care. One participant also mentioned the potential for violence albeit rare, by patients who demand an opioid prescription.

Convener participants mentioned that another factor that impacts what may be deemed as "appropriate" or "inappropriate" prescribing levels is shifting state standards. The nuts and bolts of developing opioid prescribing standards ultimately fall on state medical boards, which typically results in a high variance in standards per state. According to one convener participant, the provider community is often unaware of how frequently prescribing standards may change in his or her state. Therefore, what may be deemed "appropriate" prescribing one day could morph

into "inappropriate" prescribing over time without a provider being aware of the shift.

Finally, while the Centers for Disease Control and Prevention (CDC) offers guidelines for pain management, some convener participants believed they instilled more fear than knowledge and may, in some cases, be treated as law despite the fact they are intended to be utilized as guidelines (i.e., they are not meant to replace statutes or become the standards for coverage determination). Closing the knowledge gap from day one of training (for medical, dental, and nursing students) would ameliorate those fears. On the other hand, other convener participants believed that the CDC guidelines give providers some clarity given the inferiority of their own states' guidelines.

D. Reimbursement for Non-Opioid Pain Therapy

Convener participants generally believed that if more payers reimbursed for non-opioid alternative therapies (e.g., acupuncture, physical therapy, massages) and adjunct services (e.g., wraparound services, counseling, recovery coaches, peer support groups), access to treatment—and treatment outcomes—for those with opioid use disorder would improve noticeably. One of providers' oft-cited reasons for not prescribing non-opioid alternative therapies is the high likelihood that the patient's health insurance plan will not cover such services, including the significant amount of time that the physician's office must spend on the phone with payers to determine reimbursement status for such services. Another concern voiced by some convener participants is the maximum day limits that many payers impose upon substance use disorder treatment programs, despite a legal prohibition against such limitations for most plans under the Affordable Care Act. Convener participants noted that such limitations are not imposed on individuals requiring care for other health conditions, such as diabetes, cancer, high blood pressure, etc. Treatment for opioid use disorders should not be treated any differently.

Convener participants noted that a recent survey of state laws highlighted an interesting anomaly regarding use of alternative, non-opioid treatments for pain.[11] Per the convener participants, the study showed that not one state addressed via legislation a health care provider's initial decision to prescribe opioids to his or her patient; all such laws regarding the prescribing of opioids addressed issues and/or events occurring "after" the decision had been made to prescribe opioids. In addition, convener participants observed that some hospital drug formularies are "cobbled together" pursuant to state legislation, which can result in limited non-opioid options for providers prescribing pain treatment.

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[11] Corey S. Davis, Amy Judd Lieberman, Hector Hernandez-Delgado, Carli Suba, *Laws limiting the prescribing or dispensing of opioids for acute pain in the United States: A national systematic legal review*, Drug and Alcohol Dependence Volume 194, (Jan. 1, 2019) Pages 166-172.

In addition to disincentives to prescribing non-opioids, systems do not promote good patient education on the use of opioids. The reimbursement system deters clinical pharmacists from playing a meaningful prevention role (e.g., retail pharmacists do not get reimbursed for counseling a customer about the drugs they are receiving).

IV. Potential Solutions

Convener participants devoted a significant amount of time discussing possible solutions that might help address some of the most pressing issues identified in their conversations throughout the day-long meeting.

A. PDMP Data

Convener participants engaged in a discussion about PDMP data. Participants discussed improved data sharing through the National Association of Boards of Pharmacy's PMP InterConnect program, which facilitates the transfer of prescription monitoring programs across state lines. At the time this white paper was drafted, 46 states, the District of Columbia, and Puerto Rico participate in the PMP InterConnect program. The state of Missouri has city and county participants, and California, Hawaii, Washington, and Nebraska are prospective participants. Convener participants expressed that while PMP InterConnect provides a vehicle through which patient drug data can be shared with providers across state lines, **standardization of each state's PDMP** would help to significantly reduce the disparities in the type of information that is collected by each state.

In addition to standardizing the information that is gathered and shared through PMP InterConnect, some participants believe that **properly funding state PDMPs must become a community and political priority**. Most states' PDMPs were developed with grant money that has now been used up. Lack of funding makes it difficult to implement improvements.

Some participants expressed the opinion that **state laws that require the timely entry of relevant information into a state's PDMP will help health care providers** know they are receiving the most updated information about a patient's prescription drug history. For example, the state of California requires that pharmacies enter data within seven days of issuing an opiate prescription, while other states require data reporting within one day. Some convener participants expressed the view that the implementation, maintenance, and enforcement of such mandates requires sufficient funding.

Participants also discussed **the importance of determining who should have access to the data and why**. Some states allow law enforcement and their attorneys general to access PDMP information, which can perpetuate the stigmas and biases associated with opioid use, whether for therapeutic purposes or relating

to a substance use disorder. While some convener participants strongly opposed law enforcement and state attorneys general access to this data, others did not advocate that access should be eliminated. Overall, there was general support for the proposition that policies that are mindful of who has access to such information and for what reasons could be a step in the right direction towards destigmatizing substance use disorders. This discussion raised, but left open, the issues surrounding what should be done with PDMP data and how they can be used in a positive manner and not as a barrier to care. The discussion did not delve into other data-related issues such as the consistency of death certificate data and the collection of data related to non-fatal overdoses.

B. *Educating Early, Changing Mindsets, and Understanding Opioid Use Disorder as a Medical Condition*

Convener participants engaged in a discussion about pain and addiction education and considered the questions of what barriers with respect to such education exist now, how data can be measured on the effectiveness of such education, and who should take responsibility for it. Participants generally agreed that medical, dental, pharmacy, nursing, and other health professional schools should consider **providing a more robust level of education and training to their students** about how to 1) address their own biases related to opioid use and address the stigma; 2) handle difficult conversations with patients regarding opioid usage, substance use disorders, and appropriate pain management; 3) treat pain; and 4) treat opioid use disorders. Substance use disorders are multidimensional, complex, chronic health problems (rather than a criminal problem) with psychological, physical, behavioral, social, and economic components, all of which impact a patient's wellbeing and recovery. A participant commented that while "learning" is important, "unlearning" is important as well.

A participant shared that Yale University's medical school curriculum, for example, is committed to incorporating "teaching threads" on substance use disorders, pain medications, and pain management for its medical students through graduation. Brown University's medical school curriculum also was mentioned as an example in which medical residents throughout the length of their residencies are educated about the social determinants of health as related to opioid use and substance use disorders.

Some convener participants expressed concern that medical and other health professional school curriculums are already packed with academic and other requirements that students (as well as the school) must fulfill, and that information dissemination alone without other types of training may be insufficient. Convener participants were most enthusiastic about training that was interprofessional (team-based) in nature and which incorporated trauma-informed care; bias training; information about substance use disorders and evidence-based treatment (including harm reduction); pain treatment; co-morbid mental illness; and associated health inequities. The idea of having "pain champions" within such school

programs was also discussed. Ultimately, convener participants acknowledged that there was no "one-size-fits-all" approach to training and education.

For all health care providers, such training and education should extend through undergraduate and graduate medical education and should carry over into the provider's clinical practice. It should include becoming, at the very least, aware of and familiar with the emerging science behind the physiological and metabolic reactions to opiates as well as new developments in treatment. Further, it should include updates on emerging evidence on opiates, pain, substance use disorders and treatment effectiveness and harm reduction. Rather than using information from a PDMP in a punitive way, health care providers should use that information as a clinical tool to inform individualized treatment and facilitate patient-provider communication and trust. While specifics were not discussed, convener participants expressed that an environment of support and teamwork among providers within the health care community should be cultivated given how difficult it is to talk to patients who suffer from opioid use disorder.

Other convener participants expressed that **education and interventions regarding substance misuse and substance use disorders would ideally begin in childhood** because of the correlation between early misuse and substance use disorder development. Moreover, given the strong correlation between childhood trauma and later substance use disorders, chronic pain, and related conditions, incorporating trauma-informed care into the education of providers and other family and child professionals could reduce opioid related morbidity by reducing adverse child experiences, or responding to those experiences early to ameliorate the negative impact. Some convener participants expressed that the country's medical system is still too reactive rather than prevention-minded, and the emerging emphasis on trauma-informed care and early education about opioid misuse could help cultivate a preventive mindset.

Educating and involving the lay community, religious leaders, and the TV/movie industries can positively impact how opioid use disorder is perceived and treated going forward—i.e., as a medical condition rather than a consequence of criminal activity—in part because they represent some of the effective interventions to reducing the stigma often associated with having contact with "a person like you," As one convener participant observed, the country is at a point where awareness of the opioid crisis is evident across a variety of communities and settings, and community members are therefore often eager to help. That energy can be harnessed to educate and engage communities in advocating for effective change.

The HIV/AIDS crisis of the 1980s was mentioned as an example in which the general public's understanding and perceptions about HIV/AIDS changed—over the course of several years and with great effort—from being viewed as a consequence of moral failings to a health condition that, with proper medical care, could be managed. By the mid-1980s, TV shows were starting to introduce characters who had HIV/AIDS. The general message conveyed in these first pioneering episodes was

that HIV/AIDS could not be contracted through casual contact. Given how powerful of an impact media and advertising can have on the general public, the TV and movie industries have the ability to influence whether opioid use disorders are perceived and treated as a medical condition, or as a consequence of criminal activity. In addition to media messaging, report cards that show how major TV networks (English and Spanish-speaking) are responding to the opioid crisis can help those networks play an important role in destigmatizing opioid use disorders. Involvement and support by religious leaders through public health campaigns can also help in destigmatizing opioid addiction.

Education about opioid use should include the full spectrum of use, from therapeutic use to substance use disorders. There are significant differences between therapeutic use (i.e. appropriate use of opioids or other controlled substances to treat pain or other conditions for which the benefits outweigh the risks), misuse (i.e., using a prescription medication without a prescription or in ways inconsistent with directions, etc. for a non-intended use), and a substance use disorder ("problematic pattern of opioid use leading to clinically significant impairment or distress," according to the DSM 5). Substance use disorders may be classified as mild, moderate, or severe, depending on the number of criteria met. The distinctions are important and have a direct impact on how care is delivered to patients who use opioids or are associated with opioids, such as patients who do not use, but are viewed as drug seekers.

Convener participants expressed the view that **a comprehensive evaluation of the education received in medical school and post medical school should be considered**. There was a lot of emphasis on better educating the provider community in the discussions that took place during the convener session, but others cautioned that education alone is not sufficient and should be framed thoughtfully because medical schools are already under great pressure to fulfill current educational and national board requirements. Continuing medical education requirements are also stacking up, so it was recommended that any policy proposals be made with these existing pressures in mind. Evaluation of all the education being required or offered to the provider community should be conducted, otherwise all of the education being touted could end up being a "band-aid" solution to a very complex and multi-faceted national crisis.

C. Prescribing Practices

Many convener participants believe that the increasing number of restrictions being imposed on prescribing practices has had the unintended consequence of restricting access for the sub-population of patients who benefit from prescription opioids for pain treatment. In addition, more health care providers fear that the tightening restrictions will put their otherwise normal prescribing practices under law enforcement and state board scrutiny. Some providers have made the difficult decision to no longer treat patients with therapeutic opioids, and sometimes instituting mandatory tapers even for patients with no signs or symptoms of opioid

use disorders. Some providers are now refusing to treat patients in chronic pain, whether or not they take therapeutic opioids.

Some convener participants noted that as prescribing restrictions and overdoses have increased, the suicide rate has also increased. The ensuing discussion highlighted that there are serious—but not completely understood—relationships between opioids and suicide. A convener participant commented that the number of overdose deaths that are actually suicides are undercounted and constitutes a substantial public health issue. Another convener participant noted that patients with chronic pain are at a significantly increased risk of suicidality and are twice as likely to die by suicide. Moreover, there is growing evidence that regulation that focused on prescription opioids alone rather than substance misuse and substance use disorders may have both minimized the dangers of contemporaneous use of opioids and other drugs—such as benzodiazepines and alcohol—and worse, shifted the harm to illicit (and significantly more dangerous) drug use.

Rather than implementing regulations that take an "all or nothing" approach, which seems to be doing more harm than good, legislators should work with the health care provider community to develop policy and regulations that focus on patient-centered care that includes therapeutic opioids for well-selected patients. Law enforcement should carefully evaluate their language and messaging as well. Legislation, especially all-or-nothing mandates, alone cannot fix the crisis. Rather than focusing on supply-side prescription opioid reduction-only mandates, well thought out **regulation should take on a more holistic approach to curbing the opioid crisis**, with a focus on harm reduction and prevention and treatment of substance use disorder and related conditions.

D. Overdose Reporting; Toxicology Data

The idea of mandating opioid overdose reporting was discussed. Convener participants generally thought it would be a good idea from a public health standpoint because it would provide much needed information to an area that is currently incomplete. Some expressed concerns about the burdens on health systems and expressed that this could be viewed as "unfunded mandated chart review." However, one solution proposed for hospital overdose reporting was to **incorporate some of this information into the already required end-of-day reports submitted to state health agencies**. However, mandated new reporting would be necessary for out-of-hospital overdoses since many individuals who experience an overdose are treated by emergency medical responders but are not transferred to a hospital.

From the emergency department perspective, a policy from state health agencies that pushes for **lab testing of all overdoses** would provide a more accurate picture about the types of overdoses being treated, especially in light of the increase in fentanyl and heroin use now that access to opioid prescriptions is becoming harder to obtain, even for those who benefit from therapeutic opioids. Information

obtained through a toxicology test would help a provider make the best clinical assessment so that the individual could receive the most appropriate treatment. The reality, however, is that once an individual has been treated for an overdose in an emergency department, he/she likely will not stay to undergo a toxicology screening/lab test, and further, this could be viewed as an even more onerous unfunded mandate on hospitals than overdose reporting.

V. Increasing Access to Opioid Use Disorder Treatment

Convener participants supported efforts to expand access to MAT-focused treatment for opioid use disorder. MAT is defined by SAMHSA as "the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a 'whole-patient' approach to the treatment of substance use disorders."[12] Convener participants identified a variety of challenges to expanding access to treatment, including the following:

1. Substantial and disparate buprenorphine training requirements (eight hours for physicians, and 24 hours for nurse practitioners and physician assistants);
2. State insurance laws regarding opioid agonist therapy (OAT) that need to be re-shaped so that provider requirements are more equitable; and
3. Overregulation of buprenorphine and methadone treatment clinics and programs.

A majority of convener participants agreed that access to the MAT medications buprenorphine and methadone would be easier if there were requirements that they be covered and reimbursed. Many stated that a holistic approach (including counseling and behavioral health therapies) increases the chances for successful treatment outcomes. **Payers need to recognize that mental health and behavior therapies are reimbursement worthy** and that medical treatment alone may not be sufficient for long term success. By contrast, one convener participant commented that evidence does not necessarily reflect that behavioral therapy coupled with medication works significantly better than medication alone. In addition, some participants raised the concern that requiring counseling could be a barrier to certain patients receiving necessary MAT.

One convener participant commented that treatment is not the same as recovery. "Treatment" deals with the individual's physiological withdrawal symptoms and cravings, while "recovery" is long term and addresses the individual's psychosocial well-being, which plays an important role in helping someone overcome a substance use disorder. Many convener participants believe a holistic model of treatment is more effective in the long run, especially given the fact that individuals who suffer

[12] Substance Abuse and Mental Health Services Administration, https://www.samhsa.gov/medication-assisted-treatment.

from addictions often also suffer from severe psychosocial comorbidities, which must also be addressed. As one convener participant stated, "we need to cultivate long term durability when it comes to treatment … one year, for example, as opposed to three days."

The idea of **"bridge clinics"** are catching on and may be one way that treatment can be made more accessible. Bridge clinics provide immediate MAT and connect the individual to necessary services. In Kentucky, bridge clinics receive their core funding from SAMHSA. A participant reported that over 500 substance use disorder providers in Kentucky have agreed to give real-time availability treatment slots to patients who are ready to undergo treatment.

The topic of **MAT waivers** came up frequently in terms of making opioid use disorder treatment more accessible. Prior to the enactment of the Drug Abuse Treatment Act of 2000 (DATA 2000), only physicians could provide MAT and they had to register with the DEA as both physicians and operators of Narcotic Treatment Programs. Under DATA 2000, physicians may apply for a waiver to provide MAT in a clinical setting without having to register as an operator of a treatment program. To qualify for a waiver, the physician must meet several requirements, including eight hours of buprenorphine training. Under CARA, nurse practitioners (NPs) and physician assistants (PAs) may also apply for a waiver to provide such treatment if they meet certain requirements, including 24 hours of training. Some convener participants wondered if the waiver requirements were necessary and whether reimbursement incentives would be more useful or effective in terms of increasing access to treatment. Some recommended that burdensome waiver requirements, such as those related to training, be eliminated.

Others, however, argued that waivers and their requirements were not the main barrier to increasing access to MAT; rather, improved access should focus on 1) providing early and integrated education at all school levels (i.e., separating MAT training from general medical education might reinforce the stigmas surrounding addiction behavior); 2) alleviating fears among practicing clinicians who have waivers but choose not to prescribe MAT for various reasons (e.g., lack of reimbursement or concerns they will come under DEA scrutiny); and 3) modernizing decades of old policies (including the necessary technology so that patient privacy remains protected during information sharing), so that substance use disorders are treated as mental health issues and not as crimes. Finally, convener participants cautioned that as access to opioid treatment increases, the number of sham treatment facilities may increase as well.

Some convener participants believed **education for the *addiction recovery community* regarding MAT** was necessary as well. For example, some individuals still believe that MAT is replacing one addiction for another. In addition, while some treatment programs (e.g., peer-based 12-step programs) may sometimes be effective for one type of addiction (e.g., alcoholism), such programs may not be

effective for other types of substance use disorders (e.g, opioid use disorder). Recovery pathways must be individualized based on the type of addiction.

Participants also discussed **the impact that telemedicine could play with respect to MAT.** Convener participants discussed exploring telemedicine as another way MAT might be prescribed. MAT drugs currently can only be delivered through DEA-approved venues, such as hospitals, clinics (e.g., methadone clinic), or in physician offices. According to a convener participant, 2018 DEA statistics reflect that approximately 1,670 opioid treatment programs were in existence in the U.S. Approximately 51,000 physicians are waived and qualified to prescribe MAT, but a third of them do not. Telemedicine may therefore be one way in which access to treatment can be increased.

VI. Reducing Opioid-related Harms

Convener participant's discussed harm reduction at length including reversal of an overdose to prevent death, as well as non-fatal harms, such as incidents of hypoxia or infections from unclean syringes.

A. Naloxone—Accessibility and Cost

Many convener participants shared their concern over the rising cost of naloxone. While participants generally agreed that naloxone should be more available, opinions differed on how accessible naloxone should be to the general public (including friends and family members who have loved ones at risk of an overdose) and to all ranks of the medical profession. The associated costs and risks were weighed against the benefits of making it as common and responsive as heart defibrillators. For example, one participant asked whether broad distribution of naloxone is the best use of resources. Some factors affecting the cost and access of naloxone are:

- the possibility of over the counter availability (which could eliminate insurance coverage),
- the number of manufacturers producing the drug,
- the number of doses needed to effectuate a reversal of the overdose (some participants stated that fentanyl overdoses can require multiple naloxone doses to reverse),
- whether the product could be nonsterile, and
- use of a vaccine-model payment approach.

Many ideas were offered on how to address naloxone accessibility, including the use of drug drones (which a participant said is already being utilized in certain parts of Europe); vending machines that dispense naloxone to registered individuals (e.g., Nevada's naloxone program has vending machines located at health clinics in rural areas); developing an app that shows where the nearest naloxone dispenser is

located; making naloxone available over the counter and covered by insurance; and co-prescribing naloxone with opioid medications (e.g., Rhode Island has a co-prescribing mandate). Regarding the co-prescribing mandate, some convener participants cautioned that not everyone who is prescribed an opioid medication needs a co-prescription for naloxone—everyone reacts differently to opioids and the number of tablets prescribed may also factor into whether a co-prescription for naloxone is necessary.

Whatever the solutions might be in terms of making naloxone more widely available, there was agreement that **regular evaluation of geographic patterns of naloxone use, repeat overdose incidents, and overall mortality would help identify the highest-impact locations for naloxone distribution**.

B. Overdose Prevention Sites or Safe Injection Sites

Overdose Prevention Sites (OPS), also referred to as safe injection sites, allow individuals to consume opioids in an area where trained individuals are on hand to assist in the event of an overdose. Trained staff and resources are at the ready should something go wrong during one's consumption of an opioid or other drug. The idea is widely accepted in Canada and Europe, but the idea remains highly controversial in the U.S. For example, a convener participant relayed that political leaders, community activists, and recovery advocates in the city of Philadelphia are in a fight over whether an OPS should be established and funded in their city.

Despite the controversies surrounding establishing OPS, communities that are willing to offer one might do so on a smaller scale, build upon its successes, show that the community is benefiting from having the OPS, and grow the program incrementally. Many of the convener participants believed that the OPS was analogous to clean needle exchange programs, from the way both are stigmatized and perceived in the criminal context, to studies showing the effectiveness of such programs (for needle exchange programs, a major benefit has been the decrease in the spread of infections; for communities that offer OPSs, the major overall benefit has been a reduction in overdose fatalities). While investments in safe injection sites may raise community concerns, convener participants noted that initial data shows that they end up saving money for the community and help to prevent overdose fatalities. Another convener participant noted that putting too much emphasis on safe injection sites could jeopardize other efforts that do have more consensus, such as making naloxone more available/accessible. **More data is needed, however, as well as education for the general public regarding the purpose and effectiveness of safe injection sites.**

VII. Conclusion

The American Health Lawyers Association is grateful for the participation of so many multidisciplinary experts at its convener addressing the national opioid crisis.

These participants tackled the subject from a wide variety of angles that are not always sufficiently addressed in existing legislative policy. Recurring themes during the day included the need to avoid myopic focus on supply side approaches; the need for measures to prevent and overcome stigma against individuals with substance use disorder and those who treat them; the need to improve the scope and accuracy of data used to develop policy; the need for modifications to financial reimbursement for treatment for pain and substance use disorder; and the need to broadly approach harm reduction by adopting evidence based public health initiatives. AHLA hopes that policymakers, advocates, and health care professionals will find these comments and proposals by our convener participants to be useful in their future efforts to combat the opioid crisis.

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